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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

MAY - 3 2012

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the ORTHOLOC™ 3Di Hallux System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	February 2, 2012
Contact Person:	Leslie Fitch Regulatory Affairs Specialist (901) 867-4120
(a)(2). Proprietary Name:	ORTHOLOC™ 3Di Hallux System
Common Name:	Bone Plate System
Classification Name and Reference:	21 CFR 888.3030 – Class II
Device Product Code, Device Panel:	HRS: Orthopedic
(a)(3). Predicate Device:	K061808 - DARCO Locking Bone Plate System

(a)(4). Device Description

Wright Medical's ORTHOLOC™ 3Di Hallux System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of bones of the feet and toes. The subject plates are modified from the DARCO Locking Bone Plate System (K061808). The system contains 33 plates belonging to 1 of 4 plate styles with various sizes and options, each contoured for specific anatomy and designed for specific procedures. All plates feature polyaxial locking screw holes and k-wire holes, and some plates have non-locking compression slots. The plates are made from titanium alloy conforming to ASTM F136 or ISO 5832-3 and accept 2.7 mm and 3.5 mm locking and non-locking screws.

(a)(5). Intended Use

The ORTHOLOC™ 3Di Hallux System is intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of bones of the feet and toes. Specific examples include:

- First metatarsal osteotomies for hallux valgus correction including:
  - Opening base wedge osteotomy
  - Closing base wedge osteotomy
  - Crescentic osteotomy
  - Proximal Chevron osteotomy
  - Distal Chevron osteotomy (Austin)
- First metatarsal fracture fixation

- Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)
- Arthrodesis of the first metatarsophalangeal joint (MTP) including:
  - Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
  - Revision MTP Fusion
  - Revision of failed first MTP Arthroplasty implant

The indications statement has been tailored to the intended use of the subject device, which has fewer plates than the predicate system. The bones of the hand, wrist, ankles, and fingers included in the predicate indications statement are omitted from the indications for this system, because this system includes only plates designed for hallux procedures. The indications statement has also been modified to include specific procedures for which the system is designed. The addition of these specific examples of osteotomies and arthrodeses does not alter the intended therapeutic effect of the subject device. These specific procedures have been evaluated for safety and effectiveness through a clinical literature review.

(a)(6). Technological Characteristics Comparison

While many of the technological characteristics are the same for the subject device system and the predicate, some design changes have been made. The subject plates have a new polyaxial locking feature that offers locking up to 15° off-axis. The subject's locking feature is similar to the locking feature for ORTHOLOC™ 3Di Ankle Plating System (K102429), but has been modified for the thinner plates of this system. The subject BOW and 1st Metatarsal plates are made from titanium alloy (Ti_6Al_4V), while the corresponding predicate plates are commercially pure titanium. The titanium alloy is a stronger material.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Performance testing supports the effectiveness of the new locking feature and the new screw and shows that no new worst-case plates (in bending) are introduced in this system. The subject plate locking mechanism evaluated in this testing was found to be acceptable for off-axis mechanical screw locking up to three times as compared to a non-locking screw. Torque testing was performed on the subject 2.7 mm non-locking screw and results exceeded the minimum safety factor. Through mechanically validated FEA analysis, the worst-case subject ORTHOLOC™ 3Di plates were found not to represent a new worst-case in bending for any of the four plate families evaluated.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The new design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. Performance testing supports the effectiveness of the new locking feature and the new screw and shows that no new worst-case plates (in bending) are introduced in this system. From the evidence submitted in this 510(k) the subject device system can be expected to perform at least as well as the predicate system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY - 3 2012

Wright Medical Technology, Inc.
% Ms. Leslie Fitch
5677 Airline Rd.
Arlington, TN 38002

Re: K120359
Trade/Device Name: ORTHOLOC™ 3Di Hallux System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: February 2, 2012
Received: February 6, 2012

Dear Ms. Fitch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): Not yet assigned.

Device Name: ORTHOLOC™ 3Di Hallux System

Indications for Use:

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- First metatarsal fracture fixation
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- Arthrodesis of the first metatarsophalangeal joint (MTP) including:
  - Primary MTP Fusion due to hallux ridgidus and/or hallux valgus
  - Revision MTP Fusion
  - Revision of failed first MTP Arthroplasty implant

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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